Dornoch

Medical Systems, Inc.

Transposal Ultra Cart
Technical Manual

Model No.: UL-QD2800
w/IV Pole (optional)

Model No.: UL-DU500

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Introduction

The Transposal Ultra Fluid Cart (cart) is designed to collect surgical fluids from one patient at a time in a reusable suction device that can then be emptied, cleaned, and rinsed. The cart is also designed to enhance or replace main wall vacuum supplies in operating room suites. Two fluid collection capacity options are available. The Ultra Quad (4 reservoirs) collects up to 52-liters of fluid while the Ultra Duo (2 reservoirs) collects up to 33-liters. Once fluids are collected, the cart is connected to an Ultra Evacuation Unit (evac) to process the reservoirs.

Two manuals are provided with this equipment and are shipped with the equipment during the initial installation. Copies of these manuals are available to any Dornoch Medical Systems, Inc. (DMS) customer upon request.

The two different manuals are as follows:

> Instructions for Use Manual – This manual is designed to instruct users in the correct operation of the cart as well as safety considerations associated with the unit.
>
> Technical Service Manual – This manual includes operation instructions, installation & disconnection instructions, technical specifications, and preventative maintenance requirements for the unit.

This is the Technical Service Manual, and it is broken into eight sections including:

- *Introduction*
- *Technical Description*
- *Operation*
- *Instructions for Use*
- *Installation*
- *Maintenance*
- *Company Information*
- *Limited Warranty*

As a supplement to these two manuals, instructional video(s) are available to assist maintenance personnel in their understanding of the equipment's operation and the maintenance procedures needed. If required, DMS service personnel can be contacted 24-hours a day at 1-888-466-6633.

Important Information

Please read this manual and follow all instructions. The words WARNING, CAUTION and NOTE have special meanings and should be reviewed.

WARNING:	Disregarding WARNING information may compromise the safety of the patient and/or health care staff and may result in injury or death.
CAUTION:	Disregarding CAUTION instructions may compromise product reliability and may result in damage.
NOTE:	NOTE information supplements and/or clarifies procedural information.

A triangle with an exclamation point alerts the health care professional to read and understand the accompanying instructions, especially the operating, maintenance and safety information.

Intended Use

The intended use of the cart is to collect surgical fluids in a reusable suction device that can then be emptied, cleaned, and rinsed while providing suction independent of the facility's wall source.

Equipment Description

Carts collect up to 52-liters of surgical fluids without the need to tandem multiple suction canisters. In addition, the cart's on-board suction assist pump improves or replaces facility wall vacuum when inadequate suction is otherwise present. The cart significantly reduces employee exposure to potentially infectious body fluids, while eliminating up to 70% of Operating Room red bag waste.

The cart contains either two 16.5 Liter reservoirs or four 13 Liter reservoirs which are processed using an evac. The multiple reservoir design allows separate suction level measurement. However, the carts contain a single vacuum pump. A suction level decrease in any reservoir, due to an open port or line, may cause the other reservoir to decrease. Once the system is installed, operators use the carts to collect fluid during surgical cases and then move them to the evac where they are processed. Once the evac cycle is started, the reservoirs are automatically emptied, cleaned, and rinsed. The carts are then wiped down and, with the addition of a new single use lid or manifold, are ready for another surgical procedure.

Carts come in two model options with the main difference being the single use disposable. The two models are the Ultra Fluid Cart (UL-DU2800 – Duo with Canister Lid and UL-QD2800 – Quad with Canister Lid) and the Ultra*fleX* Fluid Cart (UL-DU500 – Duo with Cart Manifold and UL-QD500 – Quad with Cart Manifold). The 2800 configuration is designed for single patient use in each reservoir, as well as high fluid generating procedures. The standard configuration Ultra Fluid Carts use the Transposal Single Use Lid #TP-DL2800 to provide the suction to the surgical field. The other configuration option is the Ultra*fleX* Fluid Cart designed for the busy Operating Room demanding multi-patient fluid collection and high vacuum flow. The special Ultra*fleX* Fluid Cart Single Use Manifold #UL-CL500 supports these needs with a convenient, easy-to-use remove and seal design.

User/Patient Safety

WARNINGS:

- **DO NOT apply High Flow suction or allow extended exposure of suction to the tissue associated with procedures that require either no suction, low vacuum or low flow suction, for example, passive chest drainage. ALWAYS consider the type of tissue associated with the surgical procedure BEFORE using this system. Failure to comply may result in severe injury or death.**
- Before using this system, read and understand the information in this manual. Suction equipment should only be used by people that have had adequate training on the use of this type of equipment. Pay special attention to WARNING information. Become familiar with the system components prior to use.
- The health care professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique used for each patient. Dornoch Medical Systems, Inc., as a manufacturer, does not recommend surgical procedure or technique.
- DO NOT use this system outside the scope of the defined indications for use.
- DO NOT use this system for applications that require a constant vacuum level.
- The reservoir scale and fluid volume display are not diagnostic tools. DO NOT use the scale or volume display to accurately calculate the amount of fluid loss from the patient.
- Upon initial receipt and before each use, operate the equipment and inspect each component for damage. DO NOT use any component if damage is apparent.
- ALWAYS close all unused ports and remove all unused tubing to maintain optimal suction levels. The suction levels of each canister are interdependent and linked to a common vacuum source. Failure to comply may result in the unexpected reduction of suction and patient injury.
- The suction level of this product relative to its vacuum limit setting may fluctuate significantly but will not exceed its limit. DO NOT use this system if vacuum fluctuation may cause patient injury. ALWAYS consider the type of surgical procedure before using this system.
- ALWAYS follow current local regulations governing procedure-specific suction levels to remove fluid waste safely from a surgical site.
- Reservoirs are for surgical and bodily fluid collection only; do not place any items into the reservoir for disposal. Caustic or other harmful chemicals may harm the equipment and will void the warranty.
- Handling biohazard waste is potentially dangerous. ALWAYS follow current local regulations governing biohazard waste to safely handle and dispose of surgical fluid waste.
- Manifolds and suction tubing may contain surgical waste after use. ALWAYS handle these disposable accessories as "potentially infectious materials" after use. ALWAYS wear gloves and protective eye wear when removing and disposing of these disposable accessories.
- The Blood-borne Pathogens Standards, provided by the Occupational Safety and Health Association (OSHA), requires that all workers, having exposure to "potentially infectious materials", should wear the correct personal protection equipment.
- To avoid the risk of electrical shock, this equipment must be connected to electrical outlet with a protective earth ground.
- Verify all access doors are securely in place before operating this unit.
- ALWAYS follow reservoir overfill alarms to prevent overfill.
- Use only Dornoch Medical Systems, Inc. approved accessories. Do not connect items to this system that are not designed for or specified for use with this system.
- ALWAYS have more than one person unpack and lift the equipment off the shipping pallet.
- Perform recommended maintenance as indicated in these instructions. Only trained and experienced health care professionals should maintain this equipment.
- No user serviceable parts inside the unit. Contact Dornoch Medical Systems, Inc. customer service if an issue arises. Only authorized service personnel should open any of the access covers on this equipment. User operation does not require access to these areas.
- The unit is for use within the hospital and/or surgery center. The unit is moveable but is not intended to be transportable or used in the outside environment. To be used within the healthcare facility ONLY.
- DO NOT use the system with patients that are being treated with radioisotopes or hazardous chemotherapy agents.
- ALWAYS use the handle to move the cart. DO NOT push or pull the cart by grasping any other part of the outer surface. NEVER hang any heavy object from the cart handles.
- No incline planes of operation.
- ALWAYS follow reservoir overfill alarms to prevent overfill.
- DO NOT use the system if leakage of surgical fluid waste occurs. Disconnect power immediately and call Dornoch Medical Systems, Inc. Customer Service.
- DO NOT allow fluid of any kind to spill directly onto the exterior surface of the electrically-powered cart.
- DO NOT use the cart until it has been tested properly and the Evac Unit has been installed and tested properly.
- This unit uses both bleach and enzyme in its operation. When replacing bottles, always wear the appropriate Personal Protective Equipment. Use only Dornoch Medical Systems, Inc. approved Bleach and Enzyme to avoid damage to the system components.
- This equipment is not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide. Is not intended for use with AP or APG equipment.
- Hot Water Temperatures higher than 118 ^{0}F can cause damage to the unit.
- There are no known significant risks of reciprocal interference posed by the presence of this equipment or its operation in either the operating room suites or other areas when used during specific investigations and/or treatments.
- There are no known potential electromagnetic or other interferences between this unit and other devices located and/or operated within the area of the operating room suites.

Technical Description

Specifications

Table 1 – Equipment Specifications

Item	Ultra Quad (#UL-QD2800/#UL-QD500)	Ultra Duo (#UL-DU2800/#UL-DU500)
Certifications	ETL Listing - Class 1 Medical Device. Complies with the following: ▪ IEC 60601-1. General requirements for safety of medical equipment devices. ▪ IEC 60601-1-1. Collateral Standards for Medical Equipment ▪ IEC 60601-1-2. EMC & RFI compliance testing standard. ▪ IEC 60529 – Degrees of protection provided by enclosures.	ETL Listing - Class 1 Medical Device. Complies with the following: ▪ IEC 60601-1. General requirements for safety of medical equipment devices. ▪ IEC 60601-1-1. Collateral Standards for Medical Equipment ▪ IEC 60601-1-2. EMC & RFI compliance testing standard. ▪ IEC 60529 – Degrees of protection provided by enclosures.
	▪ FDA 510K Certification: K081047	▪ FDA 510K Certification: K081047
	▪ ISO 10079-1. Medical Suction Equipment – electrically powered suction equipment. (FDA standard for hospital suction systems.)	▪ ISO 10079-1. Medical Suction Equipment – electrically powered suction equipment. (FDA standard for hospital suction systems.)
	▪ CAN/CSA Standard C22.2 No. 601.1	▪ CAN/CSA Standard C22.2 No. 601.1
FDA Product Code	JCX (carts) FNY (lids)	JCX (carts) FNY (lids)
FDA Manufacturer #	1954182	1954182
Patents	Patent Pending	Patent Pending
Installation	Mobile	Mobile
Size (inch (cm))	33(84)W x 23(58)D x 55(140)H	24(61)W x 24(61)D x 55(140)H
Weight (lbs (kg))	225(102) empty; 340(154) full	195(88) empty; 268(122) full

Utilities

Power	115-120VAC, 60Hz, 4.5 amp	115-120VAC, 60Hz, 4.5 amp
Additional Cooling	None	None
Flammable Rating	Not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide.	Not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide.

Operation

Method	Connected to the facilities main vacuum system or as a standalone device.	Connected to the facilities main vacuum system or as a standalone device.
Mode	Continuous	Continuous
Performance	High Vacuum/High Flow, maximum vacuum level obtainable is 0-700mmHg. (Measured with all ports closed) If connected to hospitable suction, obtainable vacuum can be higher than 700mmHg.	High Vacuum/High Flow, maximum vacuum level obtainable is 0-700mmHg. (Measured with all ports closed) If connected to hospitable suction, obtainable vacuum can be higher than 700mmHg.
Fluid Capacity	52,000mL	33,000mL
IV Pole	6,000mL maximum fluid capacity	6,000mL maximum fluid capacity
Cleaning	Dornoch enzyme solution and Clorox bleach are used to clean the collection cylinders of the Ultra Fluid Cart.	Dornoch enzyme solution and Clorox bleach are used to clean the collection cylinders of the Ultra Fluid Cart.

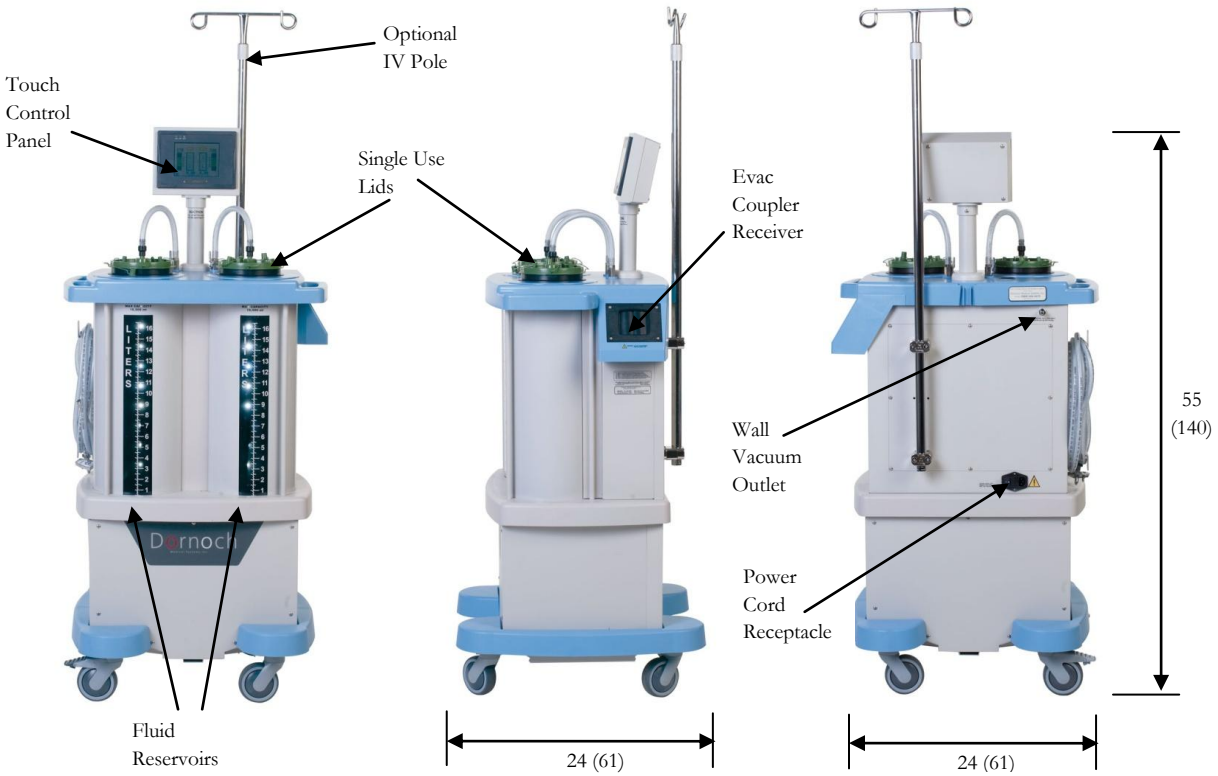


Figure 1 – Ultra Duo Cart Dimensions and Features (Dim. = inch (cm))

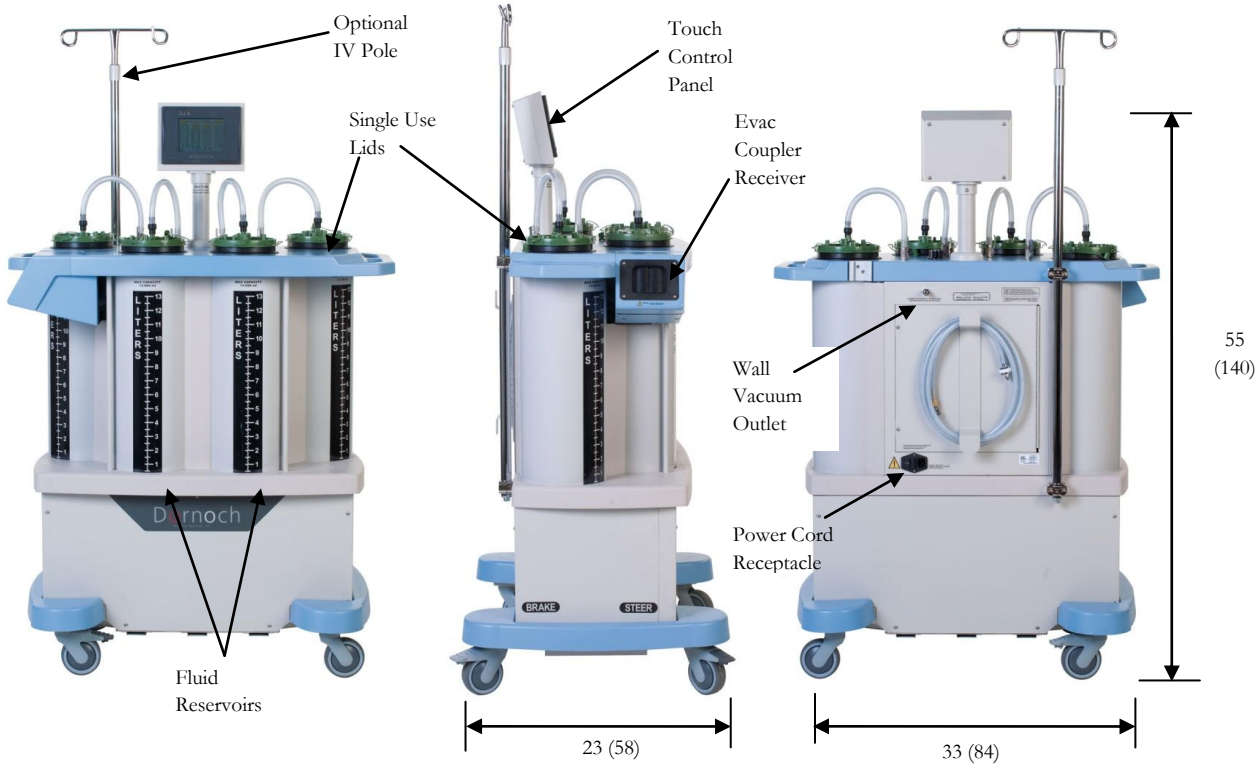


Figure 2 – Ultra Quad Cart Dimensions and Features (Dim. = inch (cm))

Operation

The Transposal Ultra Infectious Fluid Management System consists of carts for fluid collection and the evac for fluid disposal. Carts collect up to 52 liters of surgical fluids without the need to tandem multiple suction canisters. In addition, each Ultra unit's on-board vacuum pump replaces or improves facility wall vacuum performance when inadequate suction is otherwise present.

Once connected to a 120 VAC electrical outlet, cart reservoirs collect fluids from one to three separate sites. Ultra Duo Fluid Carts have two 16.5 liter reservoirs and Ultra Quad Fluid Carts have four 13.0 liter reservoirs. Reservoirs can be used with wall vacuum and/or the on-board vacuum pump.

A single use lid (Figure 3) or manifold (Figure 4) is used to make suction tube connections from the field to the cart. The Ultra Duo uses two single use lids or manifolds and the Ultra Quad uses four lids or manifolds. New lids are pressed on to the top of cart reservoirs or new manifolds are inserted into the housings. On carts with the single use lid, only one sealed, cleaned reservoir is used per patient. Carts are removed from the OR suite for processing after all reservoirs have been used, or at the end of the day. On carts with the single use cart manifold, the manifold is changed between patients to allow for multi-patient fluid collection. The carts are removed for processing at the end of every day.

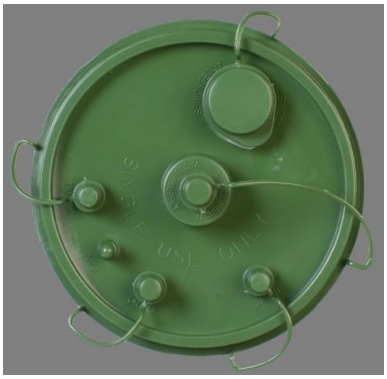


Figure 3 – TP-DL2800 Single Use Lid

Figure 4 – UL-CL500 Single Use Manifold

Cart processing is accomplished with an evac (Figure 5) located in an OR utility closet or decontamination room. Evacs empty, clean, and rinse reservoirs for reuse. The evac's water, drain, and sensor lines are easily connected to the cart using a drip-less all-in-one coupler connection. Carts are powered by the evac coupler connection during reservoir processing.

Figure 5 – Ultra Fluid Cart Connected to the Ultra Evac Unit

Safety Features

The carts have numerous built in safety features including:

- **Closed System Design.** The carts are designed to confine and contain fluids during collection and disposal of surgical fluid waste.
- **Interactive Controls.** The carts' high-tech control system guides users through unit operation while monitoring key functions.
- **Bleach Cycle Monitoring.** Continuous automatic monitoring of the bleach cycle is accomplished with electronic sensors within the evac.
- **Vacuum Protection.** Hydrophobic filters on each green single use lid or manifold prevent main line vacuum contamination. In addition, DMS's unique vacuum adapter only connects to lid or manifold protected vacuum ports.
- **Air Exhaust Protection.** Air exhausted through the on-board suction pump is filtered using a replaceable HEPA rated filter.
- **Early Warning and Overflow Protection System.** Will alert the user when the reservoir is 1000mL from full capacity, and will do the following to avoid an overfill situation.
    1. Reservoir will no longer be used and the vacuum will automatically shut off.
    2. Reservoir is then automatically vented to prevent backflow.
    3. Once the reservoir is shut off due to the Early Warning System, it must be processed with the evac in order for it to be reset for further fluid collection use.
    4. The hydrophobic filter in the bottom on the single use lid or single use cart manifold is a secondary means (mechanical) of safety to prevent liquid from getting into the vacuum line.

Note: If fluids or solids are drawn into the vacuum pump during operation, immediately discontinue use and remove the equipment from service. Contact DMS service personnel at 1-888-466-6633 to report this issue; don't continue to use the equipment.

Environmental Protection

Infectious Waste: None

Waste Disposal Accessories

There are no current accessories required for disposal from this unit.

Reusable Suction Reservoir Use and Processing

- ***Reservoir Use.***

Cart reservoirs, consisting of a reusable fluid collector and single use lid, shall be used in place of traditional disposable suction canisters/liners in surgery. Cart reservoirs are considered non-critical and non-sterile medical devices and should be handled accordingly. The fluid collection ranges for each reservoir is 0 to 13,000mL for an Ultra Quad and 0 to 16,500mL for an Ultra Duo. The accuracy of the digital readouts on the Ultra Duo and Ultra Quad is +/- 150mL. The graduations on the exterior of the reservoirs are approximations only. Record fluid volume as needed from the digital readouts on the touch screen display.

CAUTION: Reservoirs are not meant to be used in tandem as this could damage the equipment. Fluid must not be pumped directly into the reservoirs as this could cause the single use lid to become dislodged or damage the equipment.

CAUTION: DO NOT use solidifier in the cart reservoirs. It will make the cart inoperable until it can be serviced to clean out the reservoir and may cause damage to the equipment.

- ***Reservoir Processing.***

WARNING: Follow the current local regulations governing biohazard waste to safely handle and dispose of surgical fluid waste.

Carts should be processed when all of the collection reservoirs have been used or at the end of the day. Designated OR, SPD, or housekeeping personnel shall empty and clean used carts with the evac. Processing shall be accomplished in accordance with manufacturer's directions. After processing, wipe down the cart with a hospital approved disinfectant wipe (Sani-Cloth Bleach Germicidal Wipe (DMS# UL-BW100), Clorox: Germicidal Wipes or equivalent) and place clean lids onto the cart. Non-approved wipes may cause surface damage to the equipment.

- ***Bleach Verification.*** Daily visual verification of the cart/evac systems Bleach cycle shall be completed using a Verification Log Kit (#TP-VL100). Continuous automatic monitoring of the Bleach cycle is accomplished with electronic sensors within the evac. If an error is detected, the message shall be reported to an immediate supervisor.

- ***Single Use Items Storage.*** A supply of new single use reservoir lids or manifolds shall be kept in a designated clean storage area, and near any point of use.

- ***Preparing Reservoirs for Use.*** A new single use lid (TP-DL2800) or manifold (UL-CL500) shall be placed onto the reservoir in a designated clean area. The user must verify the white hydrophobic filter is in place on the lid or manifold. If it is the first case of the day or the cart has just been processed, verify the reservoirs are clean prior to installing a new single use lid.

- ***Cart Transportation.*** Used carts shall be sealed and transported to the evac for processing. Before processing the cart, verify all of the ports on the single use lids or manifolds are capped.

- ***Cart HEPA Filter.*** HEPA Filter must be replaced by approved DMS Filter. When replacing HEPA Filter, it should be treated as potentially hazardous material and disposed of accordingly.

Instructions for Use

Models DU2800 & QD2800

Fluid Collection

Step 1 – Verify fluid reservoirs are empty and clean. Ensure the unit is equipped with new single use lids. (Figure 7)

NOTE: The volume of the pre-fill fluid in the reservoir is accounted for in the displayed volume on the cart's touch screen.

Step 2 – To prevent inadvertent movement of the cart, lock the caster. Plug power cord into a wall outlet and verify that it is also plugged into the cart. Turn the power switch to the ON position. (Figure 6)

Figure 6 – Power Cord and Switch

Step 3 – Attach cart vacuum line adapter to the "Vacuum Supply" port on the single use lid. (Figure 7)

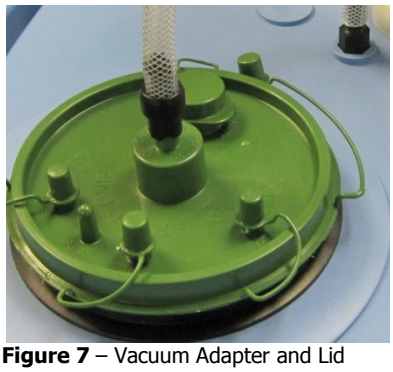


Figure 7 – Vacuum Adapter and Lid

NOTE: If cart vacuum is manually regulated, proceed to the "Manually Regulated Models" section.

Step 4 (Duo Cart) – Turn reservoir vacuum ON or OFF by pressing the desired reservoir icon on the cart's touch screen. (Figure 8)

Step 4 (Quad Cart) – Turn reservoir vacuum ON or OFF by pressing the desired reservoir icon under the "Light" buttons on the cart's touch screen. (Figure 9)

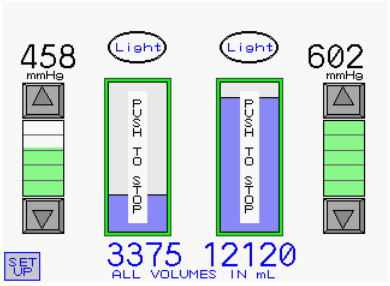


Figure 8 – DU2800 Display

Step 5 – Verify suction at the port on the green lid.

Step 6 – Load any required IV fluid onto the optional IV pole. Do not load more than 6000mL of IV fluid on the provided IV pole.

Step 7 – Attach patient tubing to port(s) on the green lid.

Warnings: DO NOT apply High Flow suction or allow extended exposure of suction to the tissue associated with procedures that require either no suction, low vacuum or low flow suction. Failure to comply may result in severe injury or death.

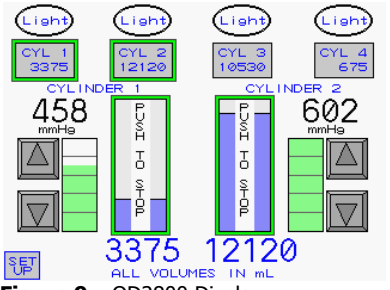


Figure 9 – QD2800 Display

Step 8 – Regulate suction using the arrows on the vacuum scales next to the appropriate reservoir image. (Figure 8 and Figure 9)

High Flow Mode (Optional Feature)
If increased suction is required during the procedure, adjust the regulated vacuum to full and then press the UP arrow one additional time to activate high flow mode. (Figure 17) To deactivate high flow mode press the down arrow to return to regulated suction.

Fluid Collection

Step 1 – Verify fluid reservoirs are empty and clean. Ensure the unit is equipped with new disposable manifolds. (Figure 10)

NOTE: The volume of the prefill fluid in the reservoir is accounted for in the displayed volume on the cart's touch screen.

Step 2 – To prevent inadvertent movement of the cart, lock the caster. Plug power cord into a wall outlet and verify that it is also plugged into the cart. Turn the power switch to the ON position.

Step 3 – Attach cart vacuum line adapter to the "Vacuum Only" port on the single-use manifold. (Figure 11)

Step 4 (Duo Cart) – Turn reservoir vacuum ON or OFF by pressing the desired reservoir icon on the cart's touch screen. (Figure 12)

Step 4 (Quad Cart) – Turn reservoir vacuum ON or OFF by pressing the desired reservoir icon under the "Light" buttons on the cart's touch screen. (Figure 13)

Step 5 – Verify suction at a manifold port.

Step 6 – Load any required IV fluid onto the optional IV pole. Do not load more than 6000mL of IV fluid on the provided IV pole.

Step 7 – Attach patient tubing to manifold port(s).

Warnings: DO NOT apply High Flow suction or allow extended exposure of suction to the tissue associated with procedures that require either no suction, low vacuum or low flow suction. Failure to comply may result in severe injury or death.

Step 8 – Regulate suction by pressing the up or down arrow on the vacuum scale next to the appropriate reservoir image. (Figure 12 and Figure 13)

High Flow Mode (Optional Feature)

If increased suction is required during the procedure, adjust the regulated vacuum to full and then press the UP arrow one additional time to activate high flow mode. (Figure 17) To deactivate high flow mode press the down arrow to return to regulated suction.

Figure 10 – CL500 Manifold Assembly

Figure 11 – Vacuum Adapter, Manifold and Cover

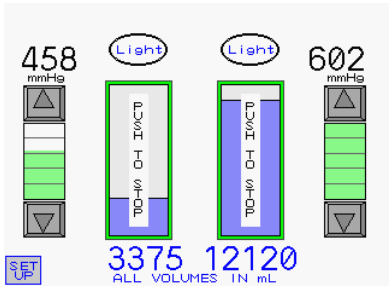


Figure 12 – DU500 Display

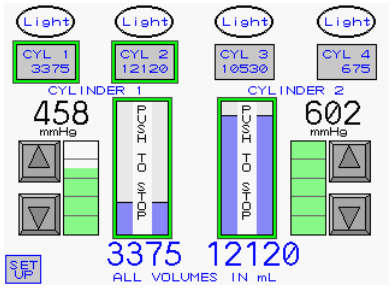


Figure 13 – QD500 Display

Preparing for the Next Procedure

To use the same reservoir for the next patient, use the following steps. Otherwise, use an empty reservoir or transport the cart to the evac for processing.

Figure 14 – Used Manifold Removal

Warning: Follow the current local regulations governing biohazard waste to safely handle and dispose of surgical fluid waste.

Step 1 – Cap all of the patient ports but leave the "Vacuum Only" port uncapped. Remove the manifold from the housing and tip it forward so the ports face slightly down. Take the cap off of the back of the housing and place it on the bottom of the manifold. (Figure 14)

Step 2 – Cap the "Vacuum Only" port and dispose of the manifold per facility red bag waste policy.

Step 3 – Reset the reservoir fluid volume to zero by pressing the digital value below the reservoir icon and following the instructions. (Number of resets limited to four total resets between cart cleanings.)

Step 4 – Insert a new manifold and proceed to Step 3 in the "Fluid Collection" section on the previous page.

Control Knob Regulated Models

Fluid Collection

Note: Follow the first 3 steps in the "Models Using Single Use TP-DL2800 Lids" section to get the cart set up for fluid collection. Then proceed as follows:

Figure 15 – Patient Tubing and Lid

Step 4 – Turn reservoir vacuum ON or OFF by pressing the desired reservoir icon on the cart's touch screen.

Step 5 – Verify suction at a port. Attach patient tubing to port(s) on the green lid. (Figure 15)

Warning: DO NOT apply High Flow suction or allow extended exposure of suction to the tissue associated with procedures that require either no suction, low vacuum or low flow suction. Failure to comply may result in severe injury or death.

Figure 16 – Vacuum Pressure Control Knob

Step 6 – Regulate suction by turning the "Increase Suction" knob clockwise to decrease counterclockwise to increase. (Figure 16)

Warning: Manual regulation of the pressure with the adjustment knob affects all in use reservoirs. Failure to comply may result in the unexpected reduction of suction and patient injury.

All Models

Transporting the Cart

After the surgical procedure is complete, the cart needs to be transported to the evac to be emptied, cleaned and rinsed.

Warnings: Always remove the disposable accessories and lower the IV pole prior to relocating the cart. Always use the handle to retain control of the cart during relocation.

Step 1 – Turn off the suction in the cart by pressing all activated reservoirs on the carts touch screen.

Step 2 – Remove patient tubing and cart vacuum lines from the green single use lid(s) and seal all ports with the attached caps.

Step 3 – Detach wall vacuum line and power cord from the wall and wind onto the cart's storage bracket. Unlock the caster to allow the cart to be transported and move it to the evac for processing.

Step 4 – Once the cart is processed and used single use lids are discarded, wipe down the cart with a hospital approved bleach wipe (Sani-Cloth Bleach Germicidal Wipe (DMS# UL-BW100), Clorox: Germicidal Wipes or equivalent) and place clean single use lids onto the cart.

CAUTION: Non-approved wipes may cause surface damage to the equipment.

NOTE: Liquid will remain in the reservoir after processing is complete. This liquid contains a small amount of enzyme for starting the breakdown of fluid waste collected during the next case.

High Flow Mode (Optional Feature)

High Flow Mode is an optional feature available on some carts. It allows a boost in suction to a customer selected reservoir when more suction is needed. Suction boost is still limited to number of lines hooked to the reservoir and if another reservoir is in use. If increased suction is required during the procedure, adjust the regulated vacuum to full and then press the UP arrow one additional time to activate high flow mode. (Figure 17) To deactivate high flow mode press the down arrow to return to regulated suction.

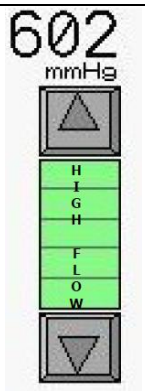


Figure 17 – High Flow Mode Indicator

General Usage Information

Single Use Lids/Manifolds and Disposable Suction Tubing

Single Use Lid: (TP-DL2800)

The single use lid has three suction ports. Any one of these ports (and up to three) can be used to collect fluids. The suction ports are labeled:

1. "Patient" this port is used for routine collection of fluids.
2. "Tandem" this port is used for routine collection of fluids.

   CAUTION: The use of this port to tandem reservoirs together is not allowed on carts as this can cause damage to the equipment.
3. "Ortho" this port is used for routine collection of fluids or used when larger suctioned particulate may occlude the Patient or Tandem ports.

Single Use Cart Manifold: (UL-CL500)

The single use manifold has three suction ports. Any one of these ports (and up to three) can be used to collect fluids. The suction ports are not labeled and are all the size of a standard "Ortho" port.

Single Use Lids and Manifolds:

WARNING: Both the TP-DL2800 lid and the UL-CL500 manifold are designed to be used for a single patient. Failure to change the item after each patient may result in the following:

1. Loss of available suction. Contaminated and/or wet filters will affect vacuum flow.
2. Cross contamination. Improper usage of single use items poses a health risk to patients and health care providers.

Disposable Suction Tubing: (Provided by the Hospital)

Any surgical suction tubing of variable diameters (sterile or unsterile) can be used to attach to single use lids/manifolds. Most suction tubing has flexible boots on the ends to accommodate different diameter suction ports or surgical devices.

CAUTION: Do not connect items that are not designed for suction systems as a safety hazard may result.

Early Warning and Overflow Protection System

The cart will alert the user when the reservoir is a 1000mL from full capacity, and will do the following to avoid an overfill situation.

- Reservoir will no longer be active and the vacuum will automatically shut off.
- Reservoir will automatically vent to prevent backflow.
- The hydrophobic filter in the bottom on the single use lid or single use cart manifold is a secondary means (mechanical) of safety to prevent liquid from getting into the vacuum line.

Optional overflow alarm sequence will do the following:

- Cart will alert the user when the reservoir is 2500mL from full capacity.
- Cart will alert the user when the reservoir is 1000mL from full capacity.
- Cart will shut vacuum off and alarm when full; user must acknowledge alarm.

Alternate Vacuum Source

Equipment Malfunction or Power Loss Situation

An alternate source of vacuum should be readily available in the event the cart can no longer provide suction to the reservoir. The cart can still be used with an external vacuum source hooked directly to the "Vacuum Port" of the single use lid. Vacuum regulation and volume readout will not be available with the cart setup in this configuration.

Rapid Full Vacuum and Specimen Collection

Application that Requires Full Suction in Ten Seconds or Less:

On the back of the unit there is a place for a canister ring holder. Place a canister ring (TP-RH100) into the holder and then either an 1800cc (TP-RC1800 (reusable)/TP-DCL1800 (disposable w/lid)) or 2800cc (TP-RC2800 (reusable)/TP-DCL2800 (disposable w/lid)) canister into the ring. Hook the black vacuum adapter from one of the reservoirs to the vacuum port on the canister lid and turn on the vacuum for that reservoir.

TP-DL2800 Application Information and Precautions

- To place a TP-DL2800 lid onto a reservoir, press it onto the lid ring with two hands working around the outside edge toward the back of the cart. Another option is to cap all of the ports and use suction to pull the lid onto the lid ring.

- When positioning the TP-DL2800 single use lid onto the cart, check that port caps are not caught under the lid. (Figure 18) Cap all ports prior to transporting the cart.

- **CAUTION:** Do NOT insert objects into the reservoir. (Figure 19) Reservoir contents are to be collected with suction only. Depositing gloves, trash, or other miscellaneous items will **CLOG** the reservoir making it unable to drain and rendering it inoperable.

Figure 18 – Port Cap Under Lid

Figure 19 – DO NOT Insert Objects

Unit Information and Error Messages

The cart provides the operator feedback for common operating errors via the display panel. The most common messages are described below. Please call DMS at 1-888-466-6633 for assistance with any error message.

Warning or Error	Action Required
Tandem Error: This message indicates fluid has been detected entering a reservoir that does not have vacuum applied.	Verify fluid lines are only hooked to reservoirs that are turned on. Do not tandem reservoirs or pump directly into reservoirs. Call service if necessary.
Temperature Errors: This message provides notice that the temperature monitoring system in the unit has detected an elevated temperature.	Finish the current surgical procedure and then remove the cart from use. Contact service once the cart is available for repair.
Processing Required: This message notifies the user that the cart has not been processed for 16 hours since it was used to collect fluid.	Finish the current surgical procedure and then process the cart with the evac.

Periodic Maintenance

Interval	Activity
Prior to each use and after each cleaning	Inspect the collection reservoirs for cracks and the two casters for failed lock and steer levers. Ensure there are no cuts in the power cord and no bent pins in the power cord receptacle. DO NOT use if the equipment if damage is present.
As required	Check the level of the enzyme and bleach in the bottles. Replace the bottles as required.

Troubleshooting Guide

Problem: Unit Will Not Operate
Possible Solutions:
1. Check that the machine is plugged into an operational outlet.

2. Check that the switch on the rear of the unit is turned on and that the power cord is all the way into the receptacle.

3. Call maintenance to replace the internal fuses.

Problem: Display is Powered, Cannot Get Vacuum Pump to Turn On
Possible Solutions:
1. Go to the setup screen and verify wall suction only button is not green.

2. Try to run the unit with wall vacuum.

3. Call DMS at 1-888-466-6633.

Problem: Volume Not Displayed on Screen
Possible Solutions:
1. Level Sensor not calibrated or defective.

2. Call DMS at 1-888-466-6633.

Problem: No Suction or Inadequate Suction
Possible Solution:
1. Verify that new single use lids have been installed. The single use lids and manifolds are each equipped with a hydrophobic filter that will close when it becomes wet. If the unit was processed and the lids have not been replaced this will block suction at the patient ports.

2. If using the cart not attached to wall suction, verify that the suction pump has been turned "ON".

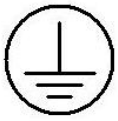
DMS Technical Service - Information

DMS Technical Service is available 24 hours a day, 7 days a week. Technicians are available in the office from Monday – Friday from 8AM until 5PM central standard time. DMS uses a paging system for any calls received at other times during the day and will get back with you as soon as possible. Please call 1-888-466-6633 and have the information below available for the technician. If possible, call with the equipment available for troubleshooting.

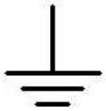
- Equipment Type (Ultra Duo, Ultra Quad, Evac or Safety Station)
- Equipment Serial Number
- Description of the problem
- Location of the equipment
- Contact information for a service technician coming to the account

Symbols & Labels

The explanation and location of all Labels, Safety Signs, Symbols and Displays used on the equipment is presented below.



Protective Earth Ground Symbol – This label is used to symbolize a protective earth ground location on the unit. There is one located on the ground from the main power cord and another located on the ground for the 24VDC power supply.

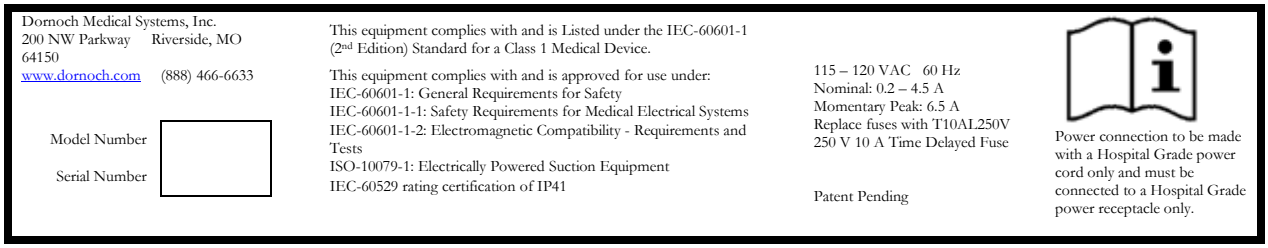


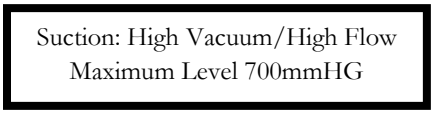
Functional Earth Ground Symbol – This label is used to symbolize a functional earth ground. They are located near all functional grounds.

Single Use Symbol – This label is used to symbolize that the product is single use only. This label is located on either of the single use lids.

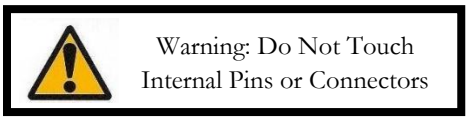
Consult Instructions Symbol – When displayed on a device, it refers the user to accompanying instructions and identifies safety and precautionary information.

Electrical Requirements, Serial Number, and Operating Instructions Label (See Below) - Located on the back of the unit under the electrical cabinet access panel. This label is used to instruct the user to the manuals. Information contained on this label: DMS contact information, serial number, ETL compliance information, electrical information, patent information and power outlet requirements.



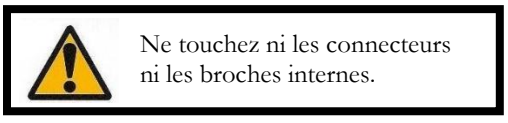


Suction Rating Label – This label is used to inform the user of the maximum level of vacuum that can be developed by the system. This label is located on the collar of the monitor pole.

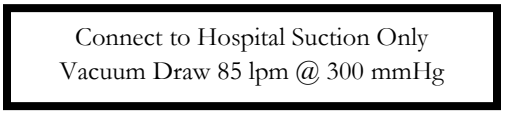


Receiver Warning Label – This label is used to warn the user of the electrical pins and connectors inside the receiver of the cart. This label is located under the receiver doors.

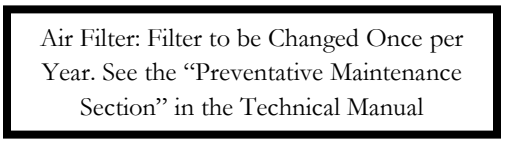
Do not connect any item here except evac coupler.



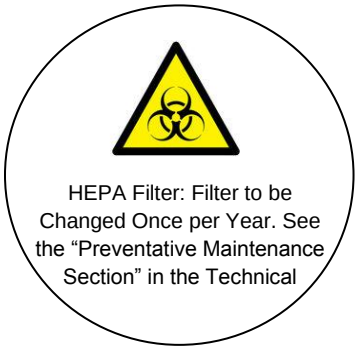
Receiver Warning Label – French version



Hospital Suction Information Label – This label is used to inform the users of the hospital suction supply requirements. This label is located under the wall vacuum connector.



Air Filter Label – This label is used to inform the users of the air filter replacement requirement. This label is located on the air filter housing.



HEPA Filter Label – This label is used to inform the users of the HEPA filter replacement requirement. This label is located on the air filter housing.

BRAKE Label– This label is used to inform the users of the Brake Caster and is located on the lower cabinet side panel above the brake caster.

STEER Label– This label is used to inform the users of the Steer Caster and is located on the lower cabinet side panel above the steer caster.

Consumables and Accessories

WARNING: Use only Dornoch-approved components and enzyme. DO NOT modify any component or accessory.

The following is a list of consumables and accessories associated with the cart.

- TP-DL2800 – Single Use Canister Lid
- UL-CL500 – Single Use Cart Manifold
- UL-IV100 – IV Pole Assembly – Mounts to the back panel of the unit and can hold up to 6000mL of fluid.
- UL-SF100 – Ultra Smoke Filter – Placed between the vacuum port on the lid and the vacuum hose to protect the cart vacuum supply.
- UL-ST100 – Ultra Specimen Trap – Specimen collection device designed for the cart. Placed on the port on the lid and then suction tubing connected to the top of the trap.
- UL-CB100 – Ultra Clot Buster – Specially formulated chemical to either prevent clotting during a rich blood procedure or to break up any clots found during processing of the cart.
- UL-BW100 – Sani-Cloth Bleach Germicidal Wipe – approved surface disinfectant wipe for the carts.

Installation

Protective Packaging & Unpacking

WARNING: ALWAYS have more than one person unpack and lift the cart off the shipping pallet.

Special measures are needed for and during transport of the unit. Carts (Duo and Quad) are heavy and should only be lifted using all three handles. The reservoirs must be emptied prior to lifting the unit or personal injury could occur. Each cart is equipped with four casters. Carts must be rolled into/out of the area they will be used during installation/de-installation.

To obtain information on transporting and temporary storage considerations call DMS at 1-888-466-6633.

Premature unpacking of the cart could risk damage to or loss of the installation items that may be sent with the unit. Contact Customer Service at 1-888-466-6633 if unpacking the unit is necessary.

Site Preparation

A DMS Installation Technician is responsible for the physical hook-up, on-site quality control testing and the initial start up of cart. No specific site preparation is required for the cart.

De-install/Disconnect Instructions

Please contact DMS at 1-888-466-6633 prior to de-installation or re-installation of carts.

If a Customer de-installs or re-installs a cart, the guidelines listed below must be followed.

- Always wear personal protective equipment, including eye protection and latex gloves, to prevent contact with potentially infectious material.
- Always unplug the unit from the wall outlet before moving equipment.
- Wipe down the unit with an approved contact disinfectant after each use.

Equipment Storage

Temperature range for proper storage is -20°C to 40 °C. If unit is to be taken out of service and stored for a prolonged period of time, evacuate all of the fluid from the reservoirs.

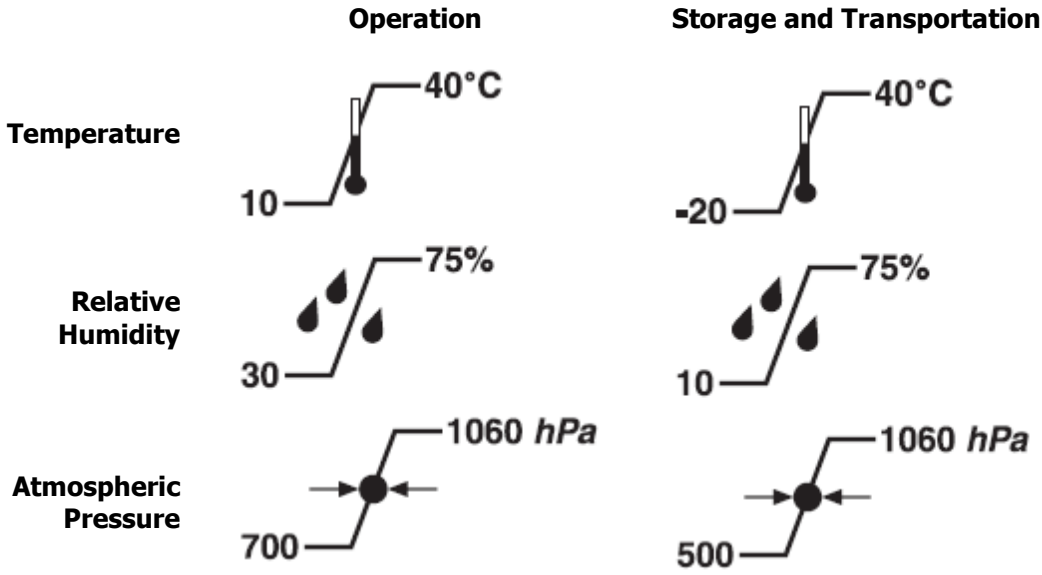


Figure 20 – Environmental Conditions

Maintenance

Qualifications for Service Personnel

Service personnel will be trained during the installation of the equipment on preventative maintenance, troubleshooting and common problems. Support for the service technicians is always available by calling Customer Service at 1-888-466-6633.

Qualifications needed to properly service products manufactured by DMS in no way allows for or authorizes any person to avoid the authorities with jurisdiction to impose additional requirements for qualifications on service personnel.

DMS recommends that all facilities service and healthcare professionals attend the Maintenance & In-Service Training sessions offered during the time of equipment installation.

All maintenance to be performed by qualified personnel only. Repairs by unauthorized individuals should not be attempted and may result in damage to or malfunction of the system or even personal injury.

Service Warnings

WARNINGS:

- Modification of this equipment is not allowed.
- When performing any service or maintenance procedures on the cart, follow all manufacturers' instructions.
- Handling biohazard waste is potentially dangerous. Wear personal protective equipment when servicing the cart.
- Prior to performing any maintenance on the cart, unplug the unit from the wall outlet. Not unplugging this unit will leave dangerous voltages & current accessible to the service personnel working on or in this machine.

NOTE: If the unit is to be moved, wipe down the outside of the unit with a hospital approved bleach wipe. (Sani-Cloth Bleach Germicidal Wipe (DMS# UL-BW100), Clorox: Germicidal Wipes or equivalent)

NOTE: Remove all fluids from the bottom of the unit's lower cabinet before returning equipment to service.

Additional Information

Upon request DMS will provide the following: Circuit Diagrams, Component Parts List, Description of Components, Calibration Instructions, and any parts information needed for repair of the unit.

Routine Maintenance

Lower Panel Removal

Remove the two blue wheel skirts, one on each side, by pulling them straight up and then out. Remove the screws that hold the panels onto the cabinet and pull it back a small amount to gain access to the ground wire. Unhook the ground wire that is attached to the panel, and then lift the panel off to completely remove.

Access Panel

Contact DMS at 1-888-466-6633 prior to removing or servicing any components that require the access panel to be removed. Removal of access panel will allow access to the electrical components underneath. Once removed the possibility of electrical shock is present. Use caution when performing any service to these components. The panel is located on the back of the unit. Note: This panel has a ground wire attached to it.

Inspections

Regularly visually inspect the unit for any signs of damaged or leaking components. If any problems are found, contact Customer Service at 1-888-466-6633 to report findings.

Replacement Items

Power Supply

There is not a substitute power supply replacement. The power supply must be replaced with the following:

- Manufacturer: Condor
- Model #: GLM75 Medical

Contact DMS for replacement parts at 1-888-466-6633.

Replacement Fuses

Two sets of replacement fuses are located on the main circuit board. Fuse specifications are as follows:

- Fuse Replacement for the main ICB power- LT5A250VP time delayed fuse.
- Fuse Replacement for the vacuum pump- MDL8A250V time delayed fuse.
- Spare fuses are provided in the upper left hand corner of the board for the above listed fuses.

The Power Entry Module contains two each – LT10AL250V fuses

Power Cord Replacement

Contact DMS for replacement only. Cord is rated for hospital use with the electrical requirements of the cart.

Fluid Paths and Wiring Diagrams

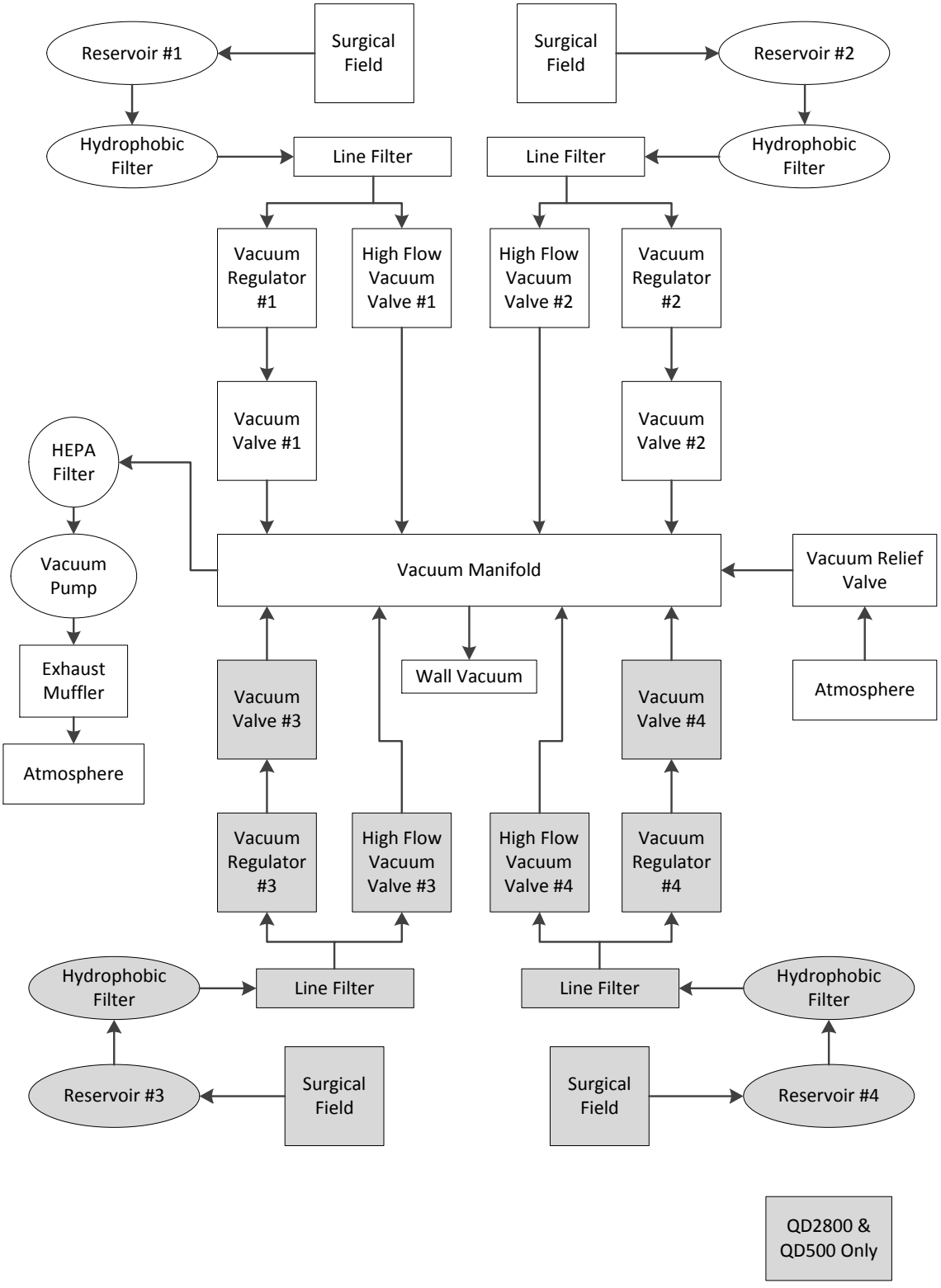


Figure 21 – Ultra Fluid Cart Vacuum Flow Diagram

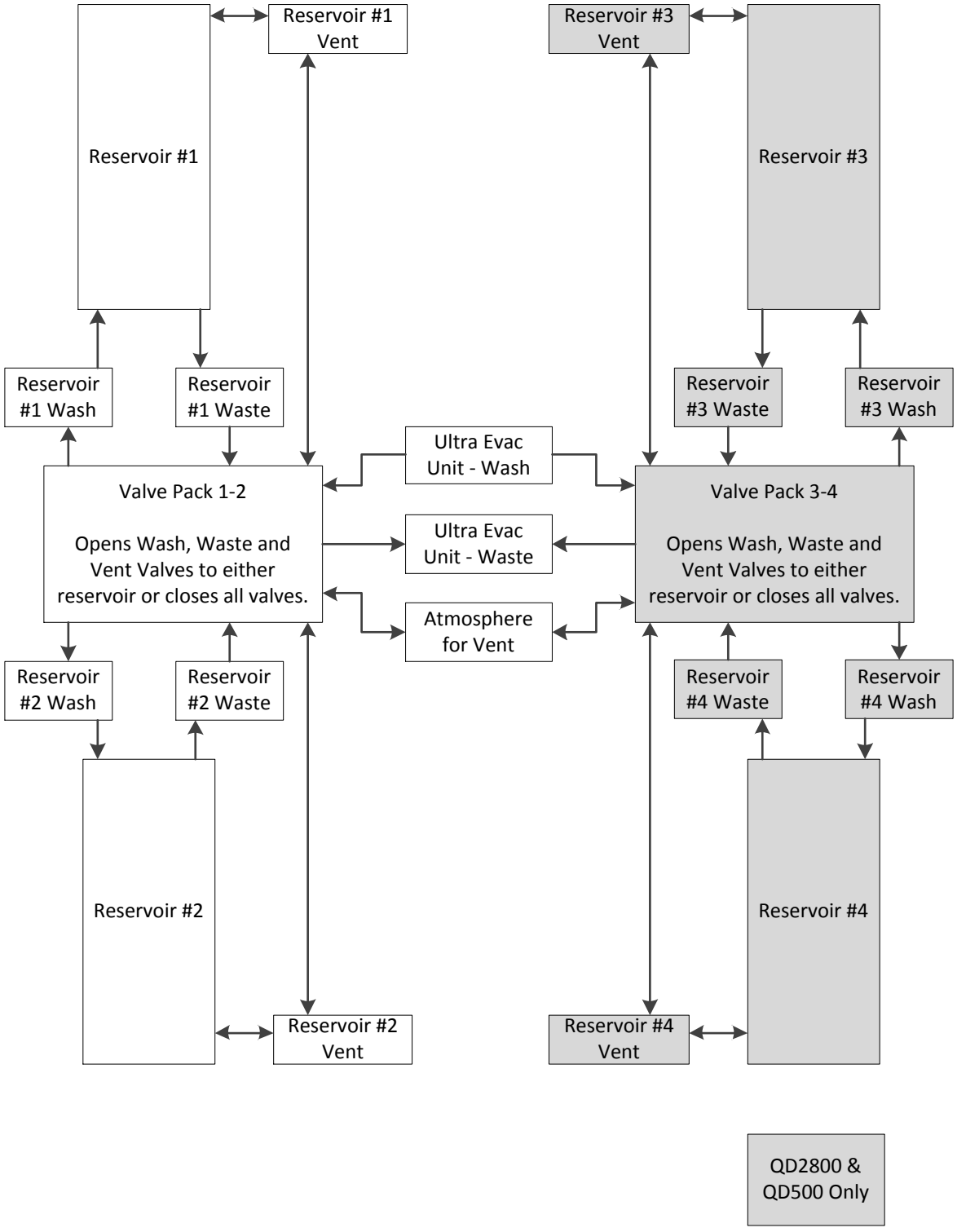


Figure 22 – Ultra Fluid Cart Fluid Flow Diagram

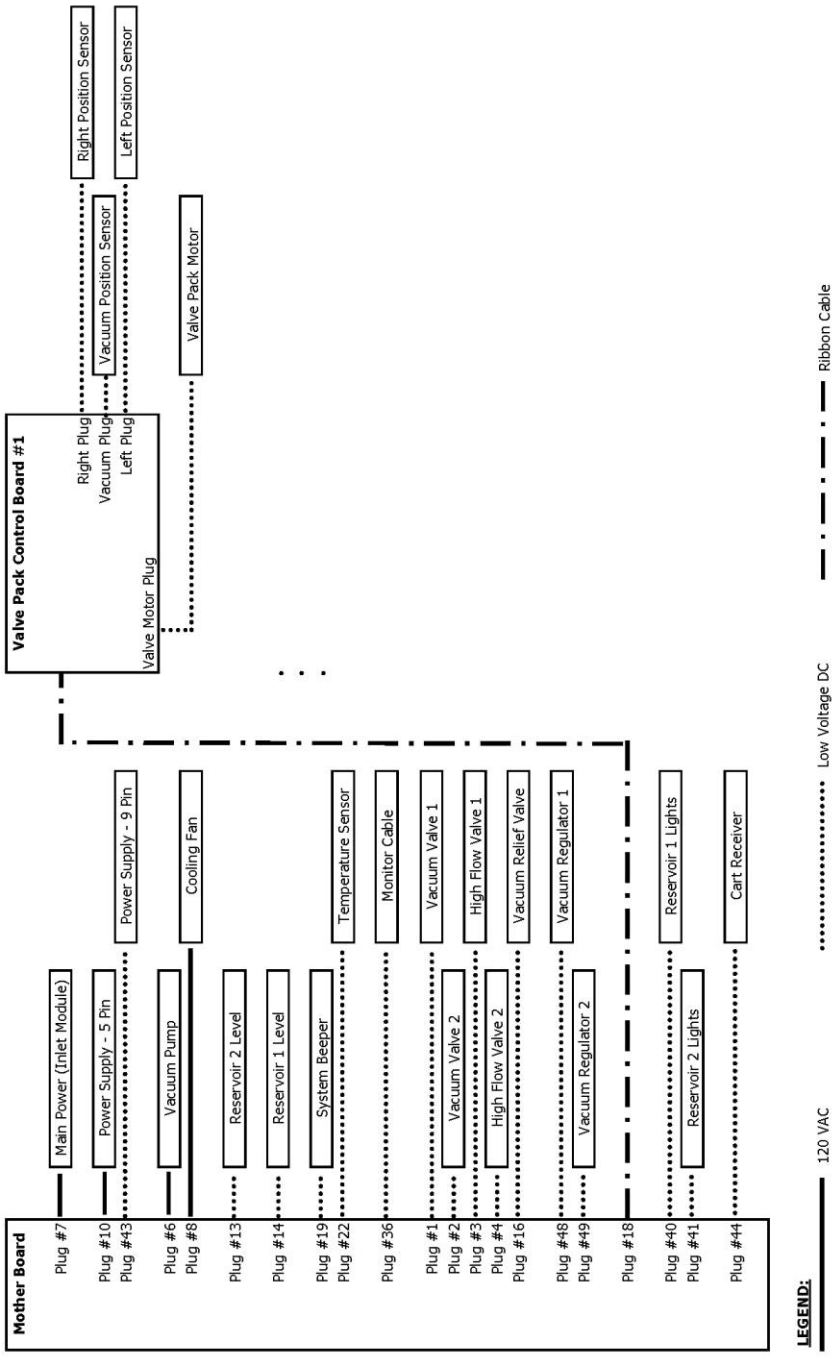


Figure 23 – Ultra Duo Cart Electrical Wiring Diagram

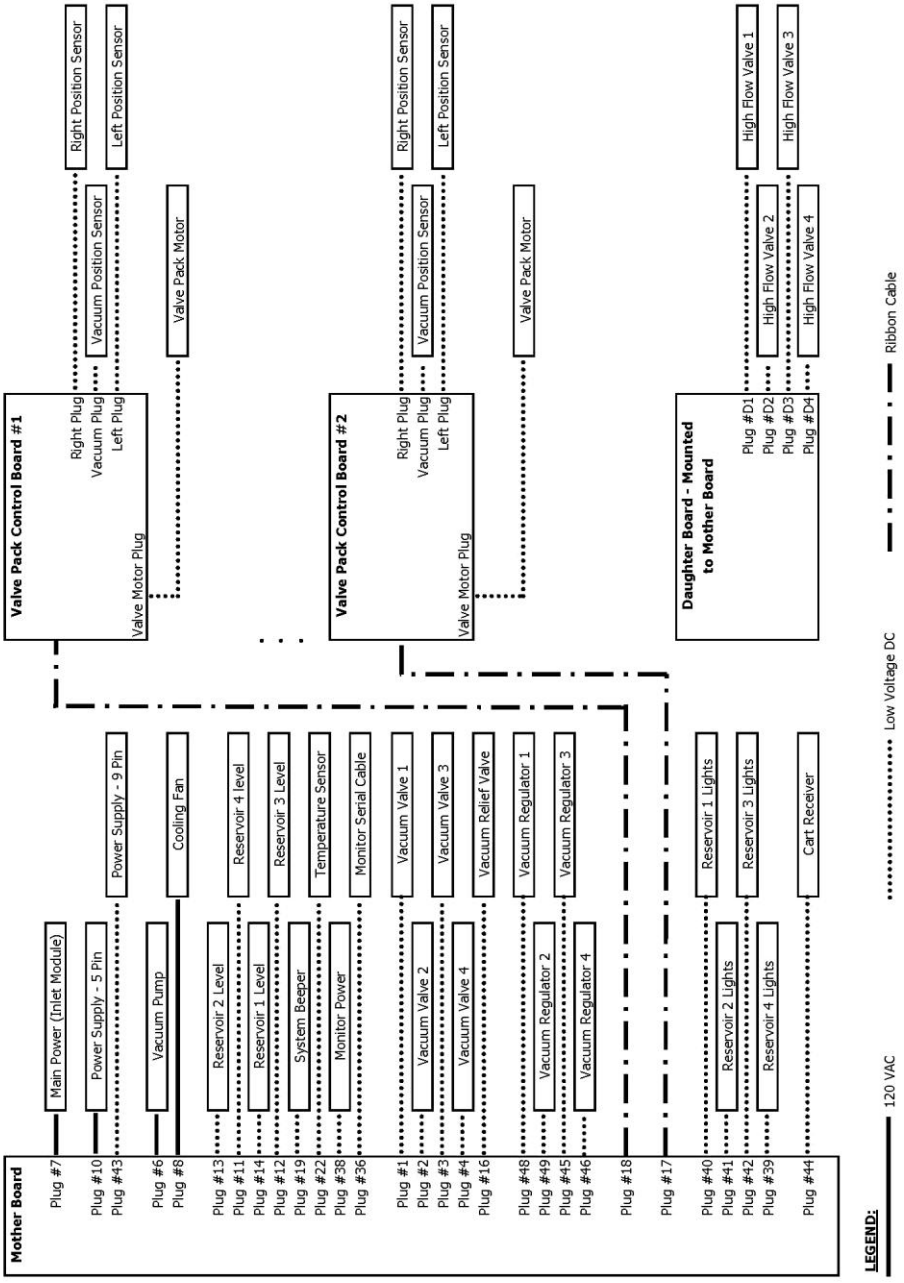


Figure 24 - Ultra Quad Cart Electrical Wiring Diagram

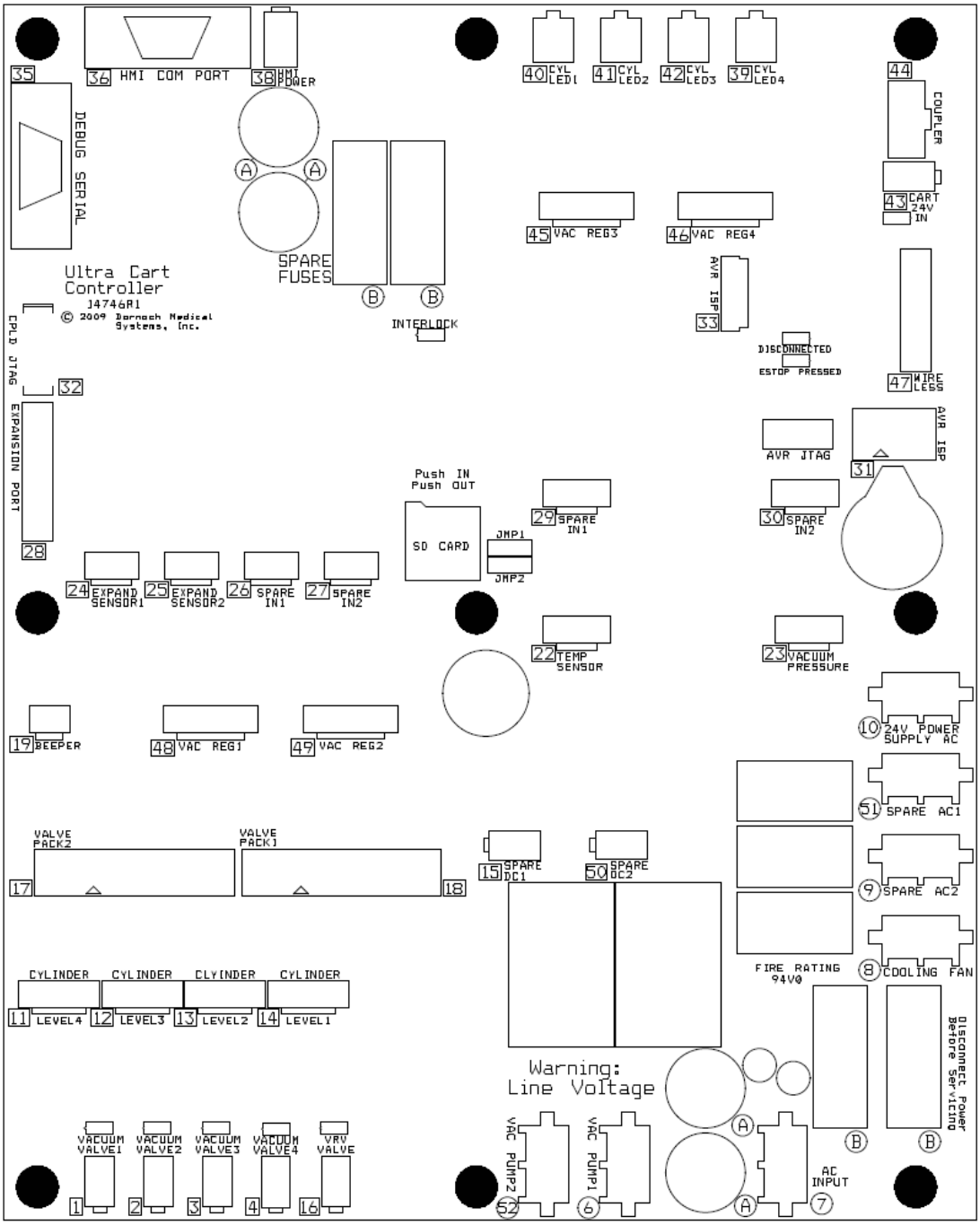


Figure 25 – Ultra Fluid Cart Mother Board Schematic

Preventative Maintenance

The cart preventative maintenance schedule is presented below. Preventive maintenance parts kits can be ordered directly from DMS by calling 1-888-466-6633.

Ultra Fluid Cart Preventative Maintenance Schedule

Table 2 – Preventative Maintenance Schedule

	Year End				Required Parts	
Procedure	**1**	**2**	**3**	**4**	**Part #**	**Quantity**
Annual PM Kit	X	X	X	X	UL-HF100	1
Vacuum Hose (If equipped)		X		X	TP-RT516	15ft (4.5m)

Note: Preventative Maintenance Procedures are available upon request by contacting Customer Service at 1-888-466-6633.

Company Information

DMS has been helping healthcare facilities responsibly manage infectious fluid waste since 1997. Starting out as the premier manufacturer for fluid waste management systems in the country, we now have installations in leading healthcare facilities nation-wide.

DMS was founded in 1995. Products are manufactured and shipped from a centralized facility and supported by a nation-wide sales force. The company's principals include individuals with extensive backgrounds in product development, management, production, and sales of medical/surgical products. Jim Dunn, a successful inventor who served as an operating room nurse for 20 years, helped design DMS products.

Contact Information

Dornoch Medical Systems, Inc.

Shipping Address:
200 NW Parkway
Riverside, MO 64150

Office Correspondence:
P.O. Box 681656
Riverside, MO 64168

Toll free: 1-888-466-6633
Phone: 1-816-505-2226
Fax: 1-816-505-1050
Web: www.dornoch.com

Limited Warranty

Dornoch Medical Systems, Inc. (hereinafter 'DMS') warrants each new Transposal Product (as listed in the Transposal Product Guide, published by DMS from time to time) which is identified as "capital equipment" on the Purchase Agreement or Trial Agreement entered into in connection herewith, to be free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of installation (the "Term"). Both parts and labor are covered for the one-year period per the conditions below.

Notwithstanding the foregoing, if any Transposal Product requiring installation is not installed by a DMS Customer Service Engineer, the term of this limited warranty shall begin 14 days (two weeks) after the date the Transposal Product has been shipped by DMS. And for any Transposal Product which does not such installation, the Term of this limited warranty shall begin three (3) days after the date the Transposal Product has been shipped by DMS. Any replacement part, including a user-installed part that has been installed in accordance with instructions provided by DMS, is subject to this limited warranty for the period remaining in the Term for the subject Transposal Product.

NOTWITHSTANDING ANYTHING TO THE CONTRARY, DMS DOES NOT WARRANT ANY OF THE FOLLOWING THAT MAY BE SHIPPED WITH OR AN INTEGRAL PART OF ANY TRANSPOSAL PRODUCT OR SUPPLIES REQUIRED TO OPERATE OR INSTALL ANY TRANSPOSAL PRODUCT: (I) ITEMS AND PRODUCTS NOT MANUFACTURED BY DMS, INCLUDING, BUT NOT LIMITED TO ENZYMATIC CLEANER, TUBING, AND ANY BACKFLOW PREVENTER; (II) ITEMS AND PRODUCTS DESIGNED FOR SINGLE USE, INCLUDING BUT NOT LIMITED TO, CANISTER LIDS AND CART LIDS; AND (III) ITEMS AND PRODUCTS IDENTIFIED AS "CONSUMABLE/CONVERSION SUPPLIES" ON A PURCHASE AGREEMENT OR TRIAL AGREEMENT ENTERED INTO IN CONNECTION HEREWITH.

DMS' liability shall be limited, at its sole option and expense, to repair or replace during DMS' normal service hours any Transposal Product which has been examined by DMS and found, in the sole discretion of DMS, to be defective. The maximum liability of DMS to any person whatsoever arising out of or in connection with the sale or use of its equipment, whether such liability arises from a claim based upon contract, warranty, tort, or otherwise, shall in no case exceed the actual value of the equipment paid by the purchaser. DMS shall not be liable to the purchaser or to any other person or entity for incidental or consequential damages.

DMS reserves the right to replace defective parts or equipment with parts which may not be identical to the original equipment or parts. Said replacement parts or equipment shall be, in the judgment of DMS, equal to or better in performance than parts or equipment initially furnished.

THIS EXPRESS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE AND MERCHANTABILITY.

DMS reserves the right to discontinue any Transposal Product, incorporate new features, specifications, colors, etc., at any time without incurring obligations to provide similar equipment or features on previously sold models of equipment or parts.

This warranty applies to the original purchaser only and is not transferable, except to the end user in a lease financed transaction, and then, if and only if, and to the extent specifically approved by DMS in writing.

This limited warranty shall be construed and interpreted in accordance with and governed by the internal laws of the State of Missouri (without giving effect to Missouri choice or conflict of law principles).

PURCHASER IRREVOCABLY AGREES THAT, SUBJECT TO DMS' SOLE AND ABSOLUTE DISCRETION, ALL ACTIONS OR PROCEEDINGS IN ANY WAY ARISING OUT OF OR RELATED TO THIS LIMITED WARRANTY WILL BE LITIGATED IN COURTS HAVING SITUS IN KANSAS CITY, MISSOURI. PURCHASER HEREBY CONSENTS AND SUBMITS TO THE JURISDICTION OF ANY COURT LOCATED WITHIN MISSOURI.

THIS WARRANTY SHALL BE VOIDED IF (I) ANY PARTY OTHER THAN A DMS CUSTOMER SERVICE ENGINEER REPAIRS OR REPLACES OR ATTEMPTS TO REPAIR OR REPLACE ANY TRANSPOSAL PRODUCT OR PARTS AND DOES NOT FOLLOW SPECIFIC INSTRUCTIONS PROVIDED BY DMS FOR SUCH REPAIR OR REPLACEMENT OF PARTS OR (II) ANY TRANSPOSAL PRODUCT (A) IS NOT USED IN ACCORDANCE WITH INSTRUCTIONS PROVIDED BY DMS (including water hook-ups at hardness levels above five (5) grains per gallon), (B) IS NOT ACCORDED REASONABLE TREATMENT BY THE PURCHASER OR (C) IS USED IN A MANNER INCONSISTENT WITH THE FOLLOWING: TRANSPOSAL ULTRA EQUIPMENT MUST NOT BE USED TO DISPOSE OF ANY SOLID MATERIAL, INCLUDING BUT NOT LIMITED TO NEEDLES, SYRINGES, HARDENED CASTING MATERIAL, TISSUE OR ANY OTHER SOLID OR SEMI-SOLID. SHOULD ANY TRANSPOSAL PRODUCT BE USED IN A MANNER INCONSISTENT WITH THE FOREGOING AND A DRAIN BLOCKAGE OCCURS, THE PURCHASER SHALL BE SOLELY RESPONSIBLE FOR THE COST OF ALL REPAIRS OF THE TRANSPOSAL EQUIPMENT AND OF ANY FACILITY DRAINAGE SYSTEMS AND ANY OTHER RELATED DAMAGE.